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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1318]

Draft Guidance for Industry on Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment.'' This draft document is intended to provide guidance on the development of drug and biological products intended to treat venous stasis ulcers, diabetic foot ulcers, pressure ulcers, and burn wounds. The draft guidance contains recommendations about labeling claims, outcome measures, trial design, and special considerations for preclinical development.

DATES: Submit written comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. For information on how to obtain copies, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Maryjane Walling, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2268;

Bette A. Goldman, Center for Biologics Evaluation and Research (HFM–500), Food and Drug

Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5098; or

Charles N. Durfor, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Chronic Cutaneous Ulcer and Burn Wounds—Developing Products for Treatment.'' This draft document is intended to provide guidance on the development of drug and biological products intended to treat venous stasis ulcers, diabetic foot ulcers, pressure ulcers, and burn wounds. The draft guidance contains recommendations about labeling claims, outcome measures, trial design, and special considerations for preclinical development.

Extensive discussions were held during two advisory committee meetings in July and November 1997 about the treatment of ulcers and burns. In response to requests from industry, the agency has developed this draft guidance. The comments received from industry, professional societies, and consumer groups represented at those meetings have been taken into consideration in drafting this guidance.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on clinical development of products for the treatment of chronic cutaneous ulcer and burn wounds. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that

individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. How to Obtain Copies

You may submit written requests for single copies of the draft guidance by sending one self-addressed adhesive label to assist the office in processing your request to:

The Office of Training and Communications,

Division of Communications Management,

Drug Information Branch (HFD–210),

Center for Drug Evaluation and Research,

Food and Drug Administration,

5600 Fishers Lane,

Rockville, MD 20857;

Or

The Office of Communication, Training and Manufacturers Assistance (HFM–40),

Center for Biologics Evaluation and Research,

Food and Drug Administration,

1401 Rockville Pike,

Rockville, MD 20852–1448,

CBER Voice Information System: 1–800–835–4709 or 301–827–1800

Fax: 1–888–CBER–FAX or 301–827–3844;

Or

The Division of Small Manufacturers Assistance (HFZ–220),

Center for Devices and Radiological Health,

Food and Drug Administration,

1350 Piccard Dr.,

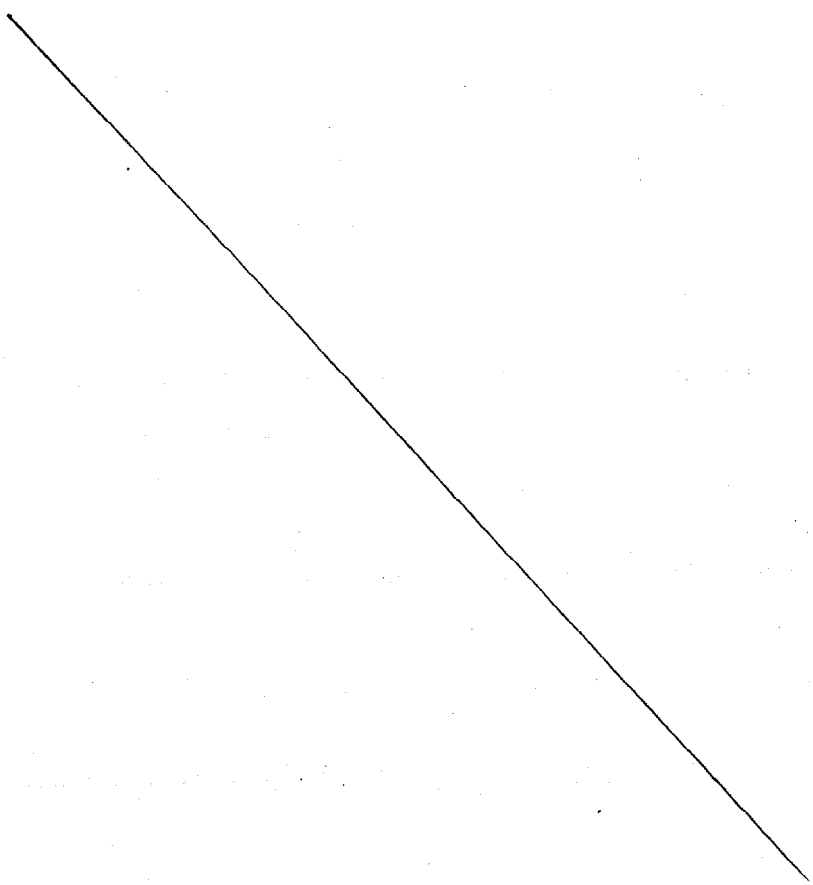
Rockville, MD 20850,

Phone: 800–638–2041,

E-mail: DSMA@CDRH.FDA.GOV,

Fax: 1–301–443–8818,

Facts-On-Demand: 800–899–0381.



An electronic version of the draft guidance also is available via the Internet at CDER's Internet site at http://www.fda.gov/cder/guidance/index.htm or at CBER's Internet site at http://www.fda.gov/cber/guidelines.htm.

Dated: 6/16/00

June 16, 2000

Margaret M. Dotzel
Associate Commissioner for Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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